EXHIBIT S

Australian Government
Department of Health
Therapeutic Goods Administration

Biomet M2a metal-on-metal total hip replacement implants

Hazard alert - higher than expected revision rate

9 February 2015

Consumers and health professionals are advised that Biomet, in consultation with the TGA, has issued a hazard alert for its M2a range of acetabular and femoral head components when used in metal-on-metal (MoM) total hip replacement implants. MoM hip implants using these components have higher than expected revision rates.

These products affected include the M2a 38 femoral head, the M2a 38 acetabular cup, and the M2a Magnum femoral head. The hazard alert also applies to the M2a Magnum tri-spike acetabular cup when used in MoM configurations.

Biomet has ceased supply of the M2a 38 system and M2a Magnum femoral head and is cancelling them from the Australian Register of Therapeutic Goods (//www.tga.gov.au/australian-register-therapeutic-goods) (ARTG).

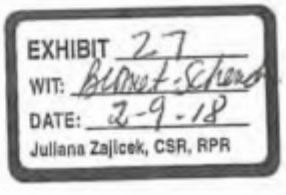
TGA analysis of Australian Orthopaedic Association's National Joint Replacement Registry (https://aoanjrr.dmac.adelaide.edu.au/) data, together with consideration of external specialist advice, has revealed that Biomet M2a metal-on-metal total hip replacement implants have a higher than expected revision rate.

Use of these implants in MoM total hip replacements has declined since 2008, with the last implantation recorded in 2011.

The TGA continues to closely monitor all MoM hip replacement systems.

Information for consumers

Patients with MoM total hip replacement implants are encouraged to review the TGA statement: Metal-on-metal hip implants: Information for patients (//www.tga.gov.au/metal-metal-hip-implants-information-patients).



Biomet has written to orthopaedic surgeons who have implanted or are treating patients who have been implanted with the affected devices providing further information about this issue, including information that will assist with following up and treating those patients.

If you are not sure what type of hip replacement you have, or if you have concerns about your hip replacement, you should contact the surgeon who performed the implantation or the hospital where the operation was performed.

If you have a MoM hip replacement and have pain in your hip or thigh, you should consult your general practitioner (GP) and/or your orthopaedic surgeon. Your health professional will usually order X-rays and, in some instances, may order further tests, such as ultrasound, MRI and blood tests.

Information for all health professionals

Health professionals who are treating patients with MoM total hip replacement implants are encouraged to review the TGA statement: Metal-on-metal hip replacement implants: Information for general practitioners, orthopaedic surgeons and other health professionals (//www.tga.gov.au/metal-metal-hip-replacement-implants).

Biomet has written to orthopaedic surgeons who have implanted or are treating patients who have been implanted with the affected devices providing further information about this issue, including information that will assist with following up and treating those patients.

Patients with any hip replacement should be followed up by the implanting orthopaedic surgeon if possible, particularly if they complain of pain and other symptoms associated with their hip implant and/or surgery.

Information for orthopaedic surgeons

Biomet has written to orthopaedic surgeons who have implanted or are treating patients who have been implanted with the affected devices encouraging them to review the TGA statement: Metal-on-metal hip replacement implants: Information for general practitioners, orthopaedic surgeons and other health professionals (//www.tga.gov.au/metal-metal-hip-replacement-implants).

The TGA recommends that you consider contacting patients who have been implanted with these devices and inform them of this issue.

Please note that the hazard alert only relates to the M2a Magnum tri-spike acetabular cup when used in MoM configurations (this device remains on the ARTG and continues to be approved for use in non-MoM hip replacements).

If you have any questions or concerns about this issue, contact Biomet by phone on 02 9878 6100 or by email at au.qa@biomet.com (mailto:au.qa@biomet.com).

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices (//www.tga.gov.au/reporting-problems#device). Your report will contribute to the TGA's monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS) (//www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

Category: Alert/Advisory, Medical devices safety
Tags: metal-on-metal, implantable devices
URL: https://www.tga.gov.au/node/288970 (//www.tga.gov.au/alert/biomet-m2a-metal-metal-total-hip-replacement-implants)